Supreme Court, U.S.
FILED
APR 12 1988
JOSEPH F. SPANIOL, JR.
CLERK

No. 87-498

IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

---

REPLY BRIEF FOR PETITIONERS

PAUL R. FRIEDMAN
DONALD B. VERRILLI, JR.
ENNIS FRIEDMAN & BERSOFF
Suite 400
1200 17th Street, N.W.
Washington, D.C. 20036
(202) 775-8100

ELLEN M. VIAKLEY *
BERGER KAPETAN MALAKOFF
& MEYERS, P.C.
5th Floor,
Law & Finance Building
429 Fourth Avenue
Pittsburgh, PA 15219
(412) 281-4200

GARY S. GILDIN
150 South College Street
Carlisle, PA 17013
(717) 243-4611

Attorneys for Petitioners

* Counsel of Record

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

ARGUMENT 1

I. The argument for per se immunity rests on the "governmental function" doctrine, which has been rejected by the Court in three prior cases. The argument is contradicted by legislative history expressly indicating Congress' intent not to except regulatory agencies from the waiver of immunity 1

II. The argument that it is the agency's "basic function", rather than particular acts of misconduct, which determines the applicability of section 2680(a) is no more than a restatement of the "governmental function" doctrine. The government's assertion that specific acts of negligence are not relevant is contradicted by the statute itself, by Dalehite and by Varig 3

III. That an agency has initial authority to promulgate regulations carrying into execution its statutory mandate does not render all subsequent conduct discretionary. This argument, if adopted, would create broad immunities for federal conduct, contrary to Congress' express intent in enacting the FTCA 5

IV. The government's argument that a finding of liability here would "eliminate" protection for regulatory functions and create unprecedented liability is baseless 8

V. The government's effort to bring this case within the shelter of Varig by generalizing about regulatory "process" is unavailing. There is no language in the statute or regulations here which confers either discretion not to examine the license appliance for demonstrated compliance or discretion to license despite noncompliance 11

TABLE OF CONTENTS—Continued

	Page
VI. Regarding the lot release approval, proof that the agency interpreted applicable regulations as mandatory in the circumstances presented here would entitle Petitioners to relief. The claim should not, therefore, be dismissed	15
VII. The government's attempt to put facts in dispute illustrates the inappropriateness of dismissal of the case under Rule 12. The extra-judicial facts asserted by the government, even if accepted, do not alter the core question presented	17
VIII. The National Childhood Vaccine Injury Act has no bearing on the issues presented here	18
CONCLUSION	20

TABLE OF AUTHORITIES

CASES:	Page
Brooks v. United States, 337 U.S. 49 (1949)	19
Conley v. Gibson, 355 U.S. 41 (1957)	17
Dalehite v. United States, 346 U.S. 15 (1953)	*passim*
Federal Election Committee v. Democratic Senatorial Campaign Committee, 454 U.S. 27 (1981)	16
Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972), *aff'd*, 500 F.2d 1059 (3d Cir. 1974)	3, 13, 16
Indian Towing v. United States, 350 U.S. 61 (1955)	2, 6
Owen v. City of Independence, 445 U.S. 622 (1980)	8
Rayonier v. United States, 352 U.S. 315 (1957)	2, 8
United States v. Muniz, 374 U.S. 150 (1963)	2, 11
United States v. S.A. Empresa Aerea De Viacao Rio Grandense (Varig Airlines), 467 U.S. 797 (1984)	*passim*

STATUTES AND REGULATIONS:	
National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755	5, 18
5 U.S.C. § 301	5
12 U.S.C. § 1817	10
28 U.S.C. § 1346(b)	4
28 U.S.C. § 2674	2
28 U.S.C. § 2680(a)	*passim*
42 U.S.C. § 247b(k)	19
42 U.S.C. § 262	10, 17
49 U.S.C. § 1421(a)	11
49 U.S.C. § 1421(c)	13
21 C.F.R. § 610.2	15, 16
21 C.F.R. § 630.17(b)	16
42 C.F.R. § 73.5	13
42 C.F.R. § 73.12	14
42 C.F.R. § 73.110(b)(5)	18
42 C.F.R. § 73.114	13
42 C.F.R. § 73.114(b)	13
42 C.F.R. § 73.115	13
42 C.F.R. § 73.117	13

TABLE OF AUTHORITIES—Continued

MISCELLANEOUS: Page

U.S. Const., Art. III, § 3 5

Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U.Chi.L.Rev. 1300 (Fall 1987) 7

REPLY BRIEF FOR PETITIONERS

ARGUMENT

The government's brief demonstrates that the only basis for immunizing the conduct challenged here would be creation of an exception providing per se immunity for regulatory conduct. Three arguments are advanced in support of creating a *per se* exception: (i) that regulatory conduct is a uniquely governmental function, entitled to *per se* immunity under the Tort Claims Act; (ii) that the Court must look not at the particular misconduct alleged, but rather at the "basic function" of the agency in determining whether immunity is preserved under section 2680(a); and (iii) that an agency's initial exercise of discretion in promulgating regulations must be found to immunize *all* subsequent conduct of the agency. It is clear from these arguments that the government's objective is to persuade the Court to import broad immunities back into a statute expressly designed by Congress to limit such immunities.

I. The argument for per se immunity rests on the "governmental function" doctrine, which has been rejected by the Court in three prior cases. The argument is contradicted by legislative history expressly indicating Congress' intent not to except regulatory agencies from the waiver of immunity.

As noted in Petitioner's opening brief, there is neither textual nor precedential support for the government's claim that section 2680(a) extends *per se* immunity to all regulatory conduct. (Pet. Br. 28-30). The government endeavors to recast the argument by asserting that regulatory activity is a "uniquely governmental function" having "no counterpart in the private sector" and on that basis enjoys *per se* immunity under the statute. (Br. 16, 19-21, 25.) [1] First, it should be noted that this argument

[1] The government also cites dicta from *Dalehite* referring to section 2680(a) as the "governmental regulatory function exception from suits". (Br. 17). However, that portion of *Dalehite* approving the governmental function test was subsequently over-

rests on section 2674 of the Tort Claims Act providing that the government shall be liable in the same manner and to the same extent as a private individual. (SA-1) The issue whether Petitioners have made out a *prima facie* case under the section has not been presented to the court.[2] Further, this Court has on three prior occasions rejected assertions that "governmental functions" enjoy *per se* immunity under the Tort Claims Act, holding that Congress did not create such as exemption and that, "There is no justification for this Court to read exemptions into the Act beyond those provided by Congress." *Rayonier v. United States*, 352 U.S. 315, 320 (1957). *See, also, Indian Towing v. United States*, 350 U.S. 61, 68 (1955); *United States v. Muniz*, 374 U.S. 150 (1963).

Petitioners' have cited legislative history plainly setting forth Congress' intent *to waive immunity for the tortious conduct of regulatory employees*, thus explicitly contradicting the government's assertion that Congress intended to preserve *per se* immunity for regulatory agencies.[3] The government responds by arguing that Congress contemplated only "ordinary tort liability", *i.e.*, negligent operation of motor vehicles, and that the government's exposure is fixed at this "traditional" concept of negligence. (Br. 15, 25, n.20). The government's posi-

---

ruled. *Rayonier, Inc. v. United States*, 352 U.S. at 315. The government also argues that prior legislative proposals specifically excepting certain agencies demonstrate Congress' intent to protect all regulatory activities. (Br. 18). To the contrary, Congress' rejection of these proposals demonstrates its intent to preserve immunity only for a particular stratum of agency conduct—that implicating Executive decision-making prerogatives.

[2] *See, Brief for Petitioners*, 2, n.1, regarding the procedural history below.

[3] The exception is "designed to preclude application of the bill to a claim against a regulatory agency . . . based upon an alleged abuse of discretionary authority . . . However, the common-law torts of employees of regulatory agencies would be included within the scope of the bill to the same extent as torts of nonregulatory agencies." *Dalehite*, 346 U.S. at 29-30, n.21 (reviewing legislative history).

tion cannot be squared with the express terms of the Tort Claims Act, which provides in section 1346(b) that liability is to be determined "in accordance with the law of the place where the act or omission occurred." Congress purposefully adopted a standard of liability linked to the states' common law, which is an *evolving* standard of liability.[4] This Court has held that "the very purpose" of the Tort Claims Act was to waive governmental immunity from tort actions and *"to establish novel and unprecedented liability."* *Rayonier, supra*, 352 U.S. at 319 (emphasis added). There is no rational basis for a finding that Congress' express waiver of immunity for the tortious conduct of employees of regulatory agencies encompasses no more than the agency's truck driver.[5]

II. The argument that is the agency's "basic function", rather than particular acts of misconduct, which determines the applicability of section 2680(a) is no more than a restatement of the "governmental function" doctrine. The government's assertion that specific acts of negligence are not relevant is contradicted by the statute itself, by Dalehite and by Varig.

The government argues that the Court may not look beyond the basic function performed by the agency in determining whether a given case falls within the ambit of section 2680(a) immunity and that the particular conduct alleged to be wrongful is not relevant to the analysis. (Br. 10, 24-25). Emphasizing "function" as opposed

---

[4] The evolving nature of Pennsylvania's common law is demonstrated by such cases as *Sinn v. Burd*, 486 Pa. 146, 404 A.2d 672, 679 (1979), observing that, "Every cause of action in tort . . . was once a novel claim" and holding that in ruling on preliminary objections for failure to state a cause of action, "the fact that the theory for recovery relied upon has not previously been sanctioned, is not conclusive."

[5] *Griffin v. United States*, 351 F.Supp. 10 (E.D. Pa. 1972), *aff'd*, 500 F.2d 1059 (1974), resulted in a $2,059,946.25 verdict against the government. If such a result were inconsistent with Congress' intent, amendment to clarify the Act's preservation of immunity for such codnuct would be expected.

to "act" is simply a semantic variation on the argument that governmental functions, including regulatory functions, are entitled to *per se* immunity under the Act. As the preceding section demonstrates, that theory is not tenable.

The government's argument is also at odds with the express language of the statute and with every decision of this Court construing the statute. Section 1346(b), for example, refers to liability in terms not of function, but of *acts or omissions*.[6] In *Dalehite* the basic *function* being performed by the War Department was patently discretionary.[7] That that was *not* a sufficient basis to support a finding of immunity is evident in the Court's extensive analysis of the specific *acts* of negligence alleged to have occurred in executing that function. The essential holding of the case is that, "*acts* of subordinates in carrying out the operations of government in accordance with official directions" are protected. *Dalehite*, *supra*, 346 U.S. at 33.[8] The same analysis of discrete conduct was undertaken in *Varig*, where the holding of the case also emphasized the focus on particular conduct; the question of immunity was found to turn on "whether the challenged *acts* of a Government employee . . . are of the nature and quality that Congress intended to shield from liability." *Varig*, *supra*, 104 S.Ct. at 2765 (emphasis added).

Thus the argument for protected "functions" is expressly contradicted by the statute, the legislative history, and the two major interpretative cases announced by this Court.

---

[6] This section is set forth at SA-1.

[7] "That the cabinet-level decision to institute the fertilizer export program laws a discretionary act is not seriously disputed.' *Dalehite*, 346 U.S. at 37.

[8] The legislative history includes reference to protected "conduct" and "discretionary acts". *Dalehite*, 346 U.S. at 29-30, n. 21 (reviewing legislative history).

III. That an agency has initial authority to promulgate regulations carrying into execution its statutory mandate does not render all subsequent conduct discretionary. This argument, if adopted, would create broad immunities for federal conduct, contrary to Congress' express intent in enacting the FTCA.

A central theme running throughout the Government's Brief is that an agency's authority to formulate regulations governing its own conduct demonstrates its discretion; that *all* conduct which "flows from" that exercise of discretion is immune; and that if agencies are not immune for all executory conduct, including violation of mandatory regulations, agencies will have a disincentive to promulgate mandatory standards. (Br. 23, 27).

First, it should be noted that the government's position runs directly counter to the constitutional duty of the Executive to "take care that the Laws be faithfully executed." U.S. Const., Art. III, § 3. The regulations, once promulgated, have the force and effect of law and must be faithfully executed.

Further, *every* agency has authority to promulgate internal regulations.[9] Adoption of the government's position—that the initial exercise of discretion in promulgating regulations immunizes all subsequent conduct—would amount to judicial repeal of Congress' waiver of immunity in the Tort Claims Act. This view is also contradicted by the language of section 2680(a), which in the first clause preserves immunity for *non-negligent* conduct undertaken *in execution of a regulation* or statute. This clause would be meaningless if the fact that regulations were promulgated at all was sufficient to trigger blanket immunity for all executory conduct.

The government cites *Dalehite* in support of its assertion that all acts which "flow from" the initial exer-

---

[9] In addition to specific grants of authority in enabling statutes, agencies have authority under 5 U.S.C. § 301 to "prescribe regulations for the government of the department . . . and performance of its business."

cise of discretion are immune. (Br. 17). The government would perpetuate the error of the panel majority below by omitting *Dalehite's* critical requirement that such conduct be *in accordance with official directions.* 346 U.S. at 36. The Court was explicit in its reason for extending immunity to such conduct. If obedient implementation of policy judgments were not covered, protection for the policy-maker would fail at the time it was most needed, i.e., when the policy was put into execution. To permit a challenge to obedient implementation of the policy would be to permit a back-door challenge to the policy itself. That rationale has no application to *disobedient* implementation of policy, and *Dalehite* does not authorize extending immunity to subordinate conduct which *violates* official directions.

Subsequently, in *Indian Towing*, 350 U.S. at 66, the Court specifically rejected the government's argument that all conduct related to the "end-objective" of a discretionary policy is protected, employing an extended hypothetical to illustrate how unworkable such a standard would be.

On a policy level, the government claims that if regulatory agencies are not protected from liability for violation even of mandatory regulations—protection which could only be achieved by a *per se* rule—agencies will have a disincentive to promulgate mandatory standards, and the public safety will thus be compromised. The government fails to explain, however, how public safety is *promoted* by allowing subordinate employees to ignore mandatory regulations designed to assure the safety of live-virus vaccines. The position advocated by the government would create a disincentive to be careful, which poses a far greater threat to effective federal regulation.

The position the government asks this Court to endorse assumes that the regulations will *not* be executed with due care. This assumption is not good policy. Congress' expectation, made explicit in the due care requirement of the first clause of section 2680(a), is directly to the

contrary. Congress obviously was not concerned that agencies would be inhibited by the imposition of liability for tortious *execution* of agency directives. If that were so, Congress would never have waived sovereign immunity. What motivated Congress was rather a separation of powers concern—to prevent the judiciary from second-guessing the reasonableness of the Executive's *policy judgment.* Separation of powers concerns are not implicated by judicial review of non-discretionary *execution* of policy judgments.

The argument that financial liability may create a disincentive to creation of stringent standards governing internal conduct may have force when applied to a private entity. However, federal agencies are created to serve a public, rather than profit-seeking purpose.[10] The government argues that regulatory agencies will be faced with "the unpalatable choice of avoiding mandatory regulations . . . or accepting the consequences in increased tort liability." (Br. 27-28). There is a third choice, the only responsible choice for administrators charged with public duties: promulgating whatever regulations are necessary to meet Congress' mandate to safeguard the public welfare and then making clear to subordinate employees that unless authority to exercise policy judgment

---

[10] Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U.Chi.L.Rev. 1300, 1328-29:

> Most important, the government presumably is not as concerned with the 'bottom line' as private industry—the reason why it decides to regulate in the first place is to ensure a greater measure of safety for employees, passengers, and other third parties. The narrow argument that imposing tort liability will cause the government to abandon such activity or promulgate only general guidelines ignores the many social and political factors other than FTCA liability which impinge on the government's regulatory activities. Because a significant political constituency will favor regulatory action, any incentives agencies may have to avoid FTCA exposure, will simply result in a greater political 'push' by Congress, most likely in its authorization statutes, to bind agencies to a mandatory regulatory framework.

in implementing the regulations is expressly conferred, they must be obeyed.

Financial responsibility for the failure of agency employees to use due care in executing non-discretionary regulations does not devolve on the agency, but "is spread among all those who contribute to the support of the Government", since the public "as a whole benefits from the services performed by government employees." *Rayonier, supra*, 325 U.S. at 320. It is not tenable to suggest that regulators will opt to protect the public purse at the expense of the public health, particularly since risks to the public purse could be wholly avoided by faithful execution of the regulatory plan. Therefore, there exists no legitimate disincentive to adoption of whatever standards the agency deems necessary to fulfill its public function. Further, this Court has previously observed that, "as an empirical matter, it is questionable whether the hazard of municipal loss will deter a public officer from the conscientious exercise of his duties," *Owen v. City of Independence*, 445 U.S. 622, 656 (1980).

Finally, and perhaps most significantly, even should the Court be concerned that such a disincentive might exist, that is not a concern that can be accommodated within the terms of the Tort Claims Act. The only rule of immunity broad enough to satisfy this argument is a *per se* rule, which cannot be squared with the statute, its legislative history, or any case decided since the statute's enactment. Congress may choose to accommodate this concern by amending the Tort Claims Act. "If the Act is to be altered that is a function of the same body that adopted it." *Rayonier, supra*, 352 U.S. at 320.

IV. The government's argument that a finding of liability here would "eliminate" protection for regulatory functions and create unprecedented liability is baseless.

The government argues that a finding of liability here would: (i) eliminate protection for regulatory functions (Br. 24); (ii) subject the government to unprecedented liability for a broad range of inspection activities (Br. 20); and (iii) enable future litigants to avoid the discretionary function exception simply by *pleading* that a mandatory regulation has been violated (Br. 26). Such arguments are baseless. This case has inherent limiting principles, arising from the extraordinary stringency of the particular statute and regulations at issue, which would preclude its application in all but a narrow class of cases, if at all.

First, it is clear that the agency could avoid liability under the principles enunciated here simply by following its own regulations. It should not be regarded as extraordinary to expect an agency to abide by the law and by its own duly promulgated rules of conduct. Petitioners are not asking the agency to be an *insurer* of vaccine safety, as the government claims. If agency employees act in conformity with non-discretionary regulations and nonetheless fail to prevent harm, the agency would *not* be subject to liability. If the statute and regulations give agency employees discretion to exercise policy judgment in implementing the regulatory plan, the agency will not be liable for errors in judgment. Protection for regulatory functions is thus not "eliminated". To the contrary, *Varig* will remain the principal case defining the scope of immunity for regulatory conduct, since it is so much broader in application that the present case. The holding here will not alter *Varig* or diminish the scope of immunity presently provided by that case.

The government next argues that "the potential liability of the United States for failure to uncover defects or improprieties pursuant to regulatory inspections is staggering," (Br. 20) and cites some two dozen inspection schemes which it claims would subject the government to unprecedented liability if Petitioners' position is sustained. However, this is *not* an inspection case; employees here were not charged with the responsibility of "uncovering improprieties" at aircraft plants or meatpacking houses or banks. Their task was much more narrowly defined: review of a license application to determine whether compliance with specified regulations

was demonstrated on the face of the document presented to them. This is not a "policeman's" role. Rather, in section 262(d) of the Public Health Service Act Congress acted to lock laboratory doors of biologic products, authorizing their release through issuance of a license *only* upon a showing of regulatory compliance. Under this statute the agency is a jailer, authorized to unlock the doors *only* when regulatory compliance is demonstrated.

A finding that the government may be subjected to liability here would thus be based on the following specific factors: (i) enabling legislation which imposes non-waivable restrictions on agency power and does not give implementing employees discretion to create exceptions to licensing requirements; (ii) regulations which define compliance standards in objective terms and do not require—or permit—the exercise of policy judgment in determining whether such standards are met; (iii) regulations which identify precisely the scope of compliance review and leave no room for policy judgment in deciding what test results are relevant to the licensing decision; and (iv) violation of non-discretionary directives by an employee acting without authority to exercise policy judgment. None of the statutory schemes cited by the government in an attempt to hector the Court with forecasts of "staggering liability" meet these criteria. In none of the cited examples could the rationale of this case be applied to subject the government to liability for "failure to uncover defects or improprieties". To the contrary, such cases would continue to fall within the ambit of immunity set forth in *Varig*.

The government nonetheless argues that future litigants would be able to circumvent the exception simply by *pleading* that mandatory regulations were violated. (Br. 20). This argument is nonsense. Take, for example, a complaint which alleges violation of "mandatory" inspection requirements under 12 U.S.C. § 1817. (Br. 20). A federal judge would take one look at the statutory language—the agency "may, in its discretion" inspect records—and dismiss the case, likely imposing Rule 11

sanctions in the process.[11] The government's claims here are wholly without foundation.

V. The government's effort to bring this case within the shelter of Varig by generalizing about regulatory "process" is unavailing. There is no language in the statute or regulations here which confers either discretion not to examine the license appliance for demonstrated compliance or discretion to license despite non-compliance.

It is significant that the government's argument is again framed in terms of "process" and largely avoids specific reference to the statute and regulations which govern this agency's conduct. The thrust of the entire Brief is rather to obscure the specific mandates at issue here by generalizing about regulatory processes. The government asserts that, "The principal lesson in *Varig Airlines* is that federal regulatory agencies have 'a statutory duty to *promote* safety' in the industries they regulate, 'not to insure it'." (Br. 21-22). The actual quote, of course, reads: "The FAA has a statutory duty to *promote* safety in air transportation, not to insure it." *Varig Airlines*, 467 U.S. at 821 (emphasis in original). The Court was not theorizing about the generalized function of regulatory agencies. It was quoting from the enabling legislation of the FAA: "The Administrator is empowered and it shall be his duty to promote safety of civil aircraft in air commerce." 49 U.S.C. 1421(a). The government concedes that the issue presented here—failure to obey mandatory regulations—"was not directly addressed in *Varig*", but finds the answer to be "nonetheless clear. The wording of the regulations does not change their essential nature, which is to promote safety by policing compliance. (Br. 23).

---

[11] "Federal rules of procedure are not so inflexible that clearly frivolous suits need embarrass (sic) prison officials or burden United States Attorneys' offices." *United States v. Muniz*, 374 U.S. 150, 164 (1961). *Muniz* indicates, however, that the government may be "subjected to the burden of pretrial preparation, discovery, and trial" to establish its defense on the merits. *Id.* at 162.

The government is wrong. The "essential nature" of the regulations at issue here is defined *not* by the enabling legislation of the FAA, but by the statute and regulations which empower *this* agency to act. And nowhere in the statute or regulations here does the word "promote" appear. The mandatory wording of these regulations is fully *consistent* with the "essential nature" of this statutory scheme, which is to insure that live-virus products which do not meet regulatory safety standards are not licensed.[12] The statutory mandate of the FAA is relevant only to demonstrate the profound *differences* in these two regulatory systems.

On a somewhat more specific level, the government argues that the process here is "indistinguishable" from the FAA process reviewed in *Varig* because: (i) like the FAA, the FDA has no duty to conduct tests, such duty resting exclusively with the manufacturer (Br. 30, 37); and (ii) the "method, mode and extent of compliance review is left by the regulations to the discretion of the FDA." (Br. 11, 29). The first of these is irrelevant; the second, wholly inaccurate.

Regarding the first, the issue here is not who *generates* the data on regulatory compliance. The issue is what is to be done—or more precisely, what the agency employee reviewing the license application is and *is not* empowered to do—on the *basis* of the data. Under the statute and regulations here, agency employees *are not authorized* to issue a license unless data submitted by the manufacturer demonstrate the vaccine's compliance with regulatory standards. This issue is absolutely unaffected by the fact that it is the manufacturer who performs the tests and generates the data upon which the licensing decision must be based.

---

[12] The word "insure" is not inappropriate in this context. However, insuring compliance with the regulations does not make the government an insurer of the safety of the vaccine. As noted in the discussion *supra*, if the regulations, though followed, are not sufficient to prevent harm, the government is not liable.

As to the second point, the government's assertion that the scope of compliance review is left by the regulations to the discretion of agency employees is wholly inaccurate. The agency's regulations properly reflect the restrictive statutory mandate in directing that: "A product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations." 42 C.F.R. § 73.5. (SA-4). The standards applicable to live poliovirus vaccine are precisely defined in section 73.110, which states that the vaccine produced by an original poliovirus strain must meet the requirements of Sections 73.114(b) (safety, as defined by neurovirulence); 73.115 (potency); and 73.117 (antigenicity). The critical safety requirement, set forth in section 73.114, precisely defines neurovirulence by five discrete criteria which are reduced to numerical values.[13] The government's argument that this language can mean something less than compliance with *all* of the standards explicitly made applicable to the vaccine is, at best, disingenuous. In *Varig*, the regulatory plan specifically authorized "spot check" inspections and specifically empowered FAA employees to choose *not* to inspect, based on their subjective judgment of the manufacturer's reliability. Express power was conferred to issue a certificate whether or not regulatory compliance was demonstrated.[14] Implementing employees were thus authorized to exercise policy judgment in determining what standards to review, whether

---

[13] The Brief of Lederle Laboratories as Amicus Curiae argues that this regulation is not mandatory because it involves "complex scientific determinations". (Br. 3-4). Scientific judgment is not policy judgment. Basic judgment *is* required to recognize that test results showing that the vaccine under review paralyzed one monkey demonstrate excessive neurovirulence, since the Reference strain paralyzed no monkeys. This judgment, however, is not within the category of "legislative and administrative decisions grounded in social, economic, and political policy" which are protected. This distinction was addressed at length by the district court in *Griffin*, *supra*, 351 F.Supp. at 30.

[14] 49 U.S.C. § 1421(c), set forth at n. 46, *Brief for Petitioners*.

to review at all, and whether to issue a certificate despite regulatory non-compliance. *No such authority is provided here.* Therefore, a directive to license *only* when regulatory standards are met cannot mean anything less than *all* standards. Test results submitted with the licensing application at issue here demonstrated that the vaccine violated the most critical requirement for licensing- the neurovirulence criteria. (J.A. 12, ¶ 17(g)). Unlike *Varig*, neither the statute nor the regulations here confer discretion to license *despite* demonstrated non-compliance.[15] The conduct here is not, therefore, protected by *Varig*.

The government's most remarkable attempt to avoid the mandatory grasp of these regulations is the argument that the regulations do not apply at all to the Sabin vaccine—that before the regulations were promulgated an independent committee found the vaccine to be "acceptable for use" (Br. 34); that this committee then "worked closely" with the department in formulating regulatory standards (Br. 35); and that "under these circumstances, new data on the Sabin strain clearly were not required by the regulations." (Br. 34). The government concludes that to contend that the Sabin vaccine does not meet criteria drafted "with it in mind" in untenable. (Br. 36) That this argument rests totally on extra-judicial "facts" will be put aside. There is no basis for exempting the Sabin vaccine from Congress' express mandate prohibiting the manufacture of vaccines without a federal license and authorizing the issuance of the

[15] The government points to 42 C.F.R. § 73.12, authorizing the Surgeon General to convene a special board "when deemed advisable" to review reports of inspections and laboratory examinations, and argues that this shows the agency's discretion to determine the scope of compliance review. (Br. 31). This section does not purport to change the requirements of licensing, but simply provides a mechanism for double-checking the process and gaining an overview of the effectiveness of agency procedures. That the Surgeon General is authorized to do *more* than the regulations require obviously does not mean that subordinate employees have discretion to do *less*.

license *only* upon a showing of regulatory compliance. If the government is correct, if in fact the requirements of the regulations do correspond with the demonstrated characteristics of the Sabin vaccine, that would provide a substantive defense at trial. It is *not* a basis for holding that regulatory compliance was not required.[16]

VI. Regarding the lot release approval, proof that the agency interpreted applicable regulations as mandatory in the circumstances presented here would entitle Petitioners to relief. The claim should not, therefore, be dismissed.

Regarding the lot release approval, dismissal of the claim is inappropriate because there are facts to be proven—the agency's own interpretation of applicable regulations as mandatory under the circumstances presented here—which would entitle Petitioners to relief. The threshold issue presented is whether the agency had a non-discretionary duty to evaluate the neurovirulence of individual monopools for regulaotry compliance and to prevent the release of a vaccine lot containing noncomplying monopools. 21 C.F.R. § 610.2, found in the introductory section of the regulations and not in the section specifically applying to live poliovirus vaccine, empowers the agency to hold vaccine lots for agency approval, but is not explicit regarding when agency approval is required. However, as applied to live poliovirus vaccines, testimony of record in the *Griffin* case demonstrated that

[16] This action is not, as the government contends, an attempt "to enter the Salk/Sabin debate on the side of Salk and to hold the government liable for coming out the otherway." (Br. 36). The allegation here has nothing to do with whether the Sabin vaccine was "safe" or whether Salk was "safer". The allegation is simply that the Sabin Type III vaccine did not comply with the agency's *regulatory definition* of safety and should not, therefore, have been licensed. Nor does this allegation threaten the government's vaccine program. There are, and were, Type III alternatives; the Sabin Type III vaccine at issue here has, in fact, been abandoned.

agency approval was required for *every* vaccine lot.[17] The Amicus Brief filed in support of the government by Lederle Laboratories states that, "Each batch of vaccine must be inspected both by the manufacturer *and by the government* before the manufacturer can release it for use, *and the government's decision is final.*" (Amicus Br. 2). Documents provided by Lederle Laboratories in discovery in other polio cases show a government stamp on *every* lot release form.

An agency's interpretation of its own regulations is entitled to deference, unless such interpretation is inconsistent with a statutory mandate or frustrates the policy Congress sought to implement. *Federal Election Committee v. Democratic Senatorial Campaign Committee*, 454 U.S. 27, 31-32 (1981). Agency policy requiring review of every live-virus vaccine lot for regulatory compliance prior to release would be fully *consistent* with Congress' expressed concern for the continuing safety of vaccines, particularly since live viruses may be genetically unstable and subject to change. The standard governing issuance of the lot release approval is demonstrated compliance with the neurovirulence criteria specifically set forth in the regulations.[18]

Further, even if the *decision* to test were found to be discretionary, whether protection extends to the implementing conduct—release of a vaccine lot which was known to be excessively neurovirulent—depends on whether the employee was acting "in accordance with

---

[17] *Griffin, supra*, 500 F.2d at 1065, n.11 (government's brief describes "tests which the manufacturer must complete prior to the submission of a lot to DBS for release"; "DBS performed its own tests on every sample of vaccine submitted").

[18] 21 C.F.R. § 630.17(b). Further authority is cited in Petitioners' opening brief at 21. It should be noted here that 21 C.F.R. § 630.17(b) is set forth at SA-10. However, as the government has already noted (Br. 39, n. 36), the section number was omitted in typesetting, and the text appears to be part of the preceding regulation, § 610.2.

official directions", or alternatively, was an "employee exercising discretion". *Dalehite*, 346 U.S. at 33, 36.

Dismissal of this claim is appropriate only if it appears beyond doubt that Petitioners can prove no set of facts in support of the claim which would entitle them to relief. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). Because there do exist facts to be proven which would entitle Petitioners to relief, *e.g.*, agency interpretation of the regulation as mandatory under these circumstances, dismissal of the claim was error.

VII. The government's attempt to put facts in dispute illustrates the inappropriateness of dismissal of the case under Rule 12. The extra-judicial facts asserted by the government, even if accepted, do not alter the core question presented.

Among the government's factual contentions is the claim that a product license is issued only for the vaccine itself and is not required for a seed virus. (Br. 31-32.) At the same time, the government admits that seed viruses do require agency "approval." (Br. 36, n.33). This is the first time the government has contested the point. The issue was presented in identical terms to the court of appeals and was not disputed. In any event, whether the product for which a license is required is a virus strain, seed virus or vaccine does not change the core question presented—whether issuance of a license for a live poliovirus product which was known not to comply with regulatory safety standards is protected conduct. We contend that it is not, based on the principles enunciated in Petitioners' opening brief and discussed in the earlier sections of this brief. On this issue, the record presently before the Court compels the holding that: *under section 262(d) of the Public Health Service Act and following regulations, issuance of a license for a live poliovirus product which is not demonstrated to be in compliance with all regulatory requirements applicable to the product is not immune conduct under section 2680(a)*

of the Tort Claims Act. The licensing claim should proceed to trial.

Whether or not a license is required for a seed virus does affect one of the subsidiary issues presented, i.e., whether failure to revoke the license when the seed demonstrated a change in neurovirulence is actionable. It is obviously correct that if a license was not required for the seed virus, there can be no contention that the agency is liable for having failed to revoke it.[19] However, the government has admitted that agency "approval" *is* required for each seed virus. Under the circumstances presented, dismissal of the claim was error. Petitioners respectfully submit that this issue should be remanded with instructions to develop a factual record on the following points regarding the seed virus: (i) the nature of the required government approval; (ii) whether the principles governing the licensing issues should apply to resolution of the question whether the agency's "approval" of a non-complying seed virus is immunized conduct; and (iii) whether the requalification requirement of 42 C.F.R. § 73.110(b)(5) (SA-7) is a non-discretionary directive to revoke the "approval" when a change in the seed's neurovirulence has been demonstrated.

VIII. The National Childhood Vaccine Injury Act has no bearing on the issues presented here.

The government's argument that the Vaccine Act was intended to provide an exclusive remedy for vaccine injuries and otherwise demonstrates Congress' intent that

[19] The government confuses the revocation issue with the abandoned allegation that the agency was liable for failing to order the withdrawal of vaccines that had *already been released* for public distribution. (Br. 6, n.7). (*See, Brief for Petitioners*, 7, n. 18 for a summary of pertinent procedural history on this point.) The seed virus was never subject to release; it remained in the laboratory and in use for production of vaccine monopools. The allegation is that *before production* of the monopol that paralyzed Kevan, the seed demonstrated a change in neurovirulence, requiring that its license, or "approval", be revoked. These issues are entirely distinct.

tort actions against the government are barred is fallacious. First, as this Court has previously held, "there is nothing in the Tort Claims Act . . . which provides for exclusiveness of remedy." The Court cannot "pronounce a doctrine of election of remedies, when Congress has not done so." *Brooks v. United States*, 337 U.S. 49, 53 (1949). The Vaccine Act was not even passed until seven years after this litigation commenced and has no effect on the remedies available to Kevan Berkovitz. In fact, the Vaccine Act presently offers *no* remedy to *any* injured person, since it has never been funded. To argue that the Act presents any obstacle to the maintenance of this action is irresponsible.

As the government correctly notes, the Act was passed in response to threats by vaccine manufacturers to stop producing vaccines unless the government took steps to mitigate the manufacturers' potential liability for vaccine-related injuries. The central purpose of the Act was thus to appease private manufacturers in order to assure the continued availability of vaccines. The Act does not accomplish this purpose by erecting a bar to civil actions. Rather, section 2111(2) provides that the Act's no-fault administrative remedy must be pursued *before* civil actions against vaccine manufacturers may proceed, the premise being that injured persons will elect this "guaranteed compensation package" and voluntarily relinquish the "more uncertain remedy" available in tort. (Br. 43). The Act thus restrains, but does not prohibit, civil process against those entities which threaten the government's immunization policies, *i.e.*, vaccine manufacturers. The Act has no effect on civil actions against any parties outside that class, including physicians subject to liability for having administered the vaccine.

That the Act does not contain specific references to FTCA actions is, therefore, not surprising; the omission is fully consistent with the Act's exclusive protection of vaccine manufacturers. In such a context the government's argument that the Act is silent as to FTCA ac-

tions "presumably because Congress viewed the discretionary function exception as a bar to such suits" has no foundation.[20]

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

PAUL R. FRIEDMAN
DONALD B. VERRILLI, JR.
ENNIS FRIEDMAN & BERSOFF
Suite 400
1200 17th Street, N.W.
Washington, D.C. 20036
(202) 775-8100

ELLEN M. VIAKLEY *
BERGER KAPETAN MALAKOFF
& MEYERS, P.C.
5th Floor,
Law & Finance Building
429 Fourth Avenue
Pittsburgh, PA 15219
(412) 281-4200

GARY S. GILDIN
150 South College Street
Carlisle, PA 17013
(717) 243-4611

Attorneys for Petitioners

* Counsel of Record

---

[20] The express waiver of the discretionary function exception in the swine flu legislation, 42 U.S.C. § 247b(k)(2) evinces an acceptance of liability for the policy judgment of the agency and would thus provide compensation when the agency's regulations, even though complied with, were not sufficient to protect against the harm of vaccine injury.